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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,904	09/10/2003	Rosana Kapeller-Libermann	MPI00-010P1RCP1M	3441

30405 7590 12/20/2006

MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,904	KAPELLER-LIBERMANN, ROSANA	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *RCE request filed 10/13/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6,12,13,15,16,21 and 23-35* is/are pending in the application.

4a) Of the above claim(s) *29-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,12,13,15,16 and 23-28* is/are rejected.

7)☒ Claim(s) *21 and 35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A **request for continued examination (RCE)** under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/2006 **has been entered**.

Claims 1-4, 7-11, 17-20, 22 have been canceled. Claims 5-6, 15-16, 21, and 28 are still at issue and are present for examination.

Applicants' arguments filed on 10/13/2006 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

DETAILED ACTION

Claims 12-13, 23-28 and 35 were rejoined with the elected invention. However, claims 29-34 which are directed to a method of use of a polypeptide in a whole cell, which is not isolated is withdrawn as drawn to non-elected invention (see also previous office action). **Claims 5-6, 12-16, 21, 23-28 and 35 are under examination on the merits.**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6, 12-13 and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "a kinase activity" In claim 5 (and its dependent claims 6, 12-13 and 23-26) is unclear. Applicant has defined the 14172 polypeptides at page 10 of the specification to contain a kinase motif for serine/threonine. Since kinases are classified based on their specific kinase motives it is assumed that by said term is restricted to serine/threonine kinase activity. If applicant has another or broader definition for said term he/she is required to specify said definition and specific support thereof, in response to this office action.

Claims 15-16, 27-28 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 15 (and its dependent claims 16, 27-28) the term "an activity of the polypeptide " is unclear. Said phrase is interpreted to refer to "an activity" of "a kinase activity" of polypeptides of claim 5 but the metes and bounds of "an activity" beyond ATP-binding and phosphorylation of substrates such as Myelin basic protein (MBP), serine/threonine is unclear.

In traversal of this reaction applicant has amended claim 15 and argues the following : (1) in paragraph [0088] of the specification he/she has support for many kinase activities from the sub molecular level (e.g. activity ascribed to subdomain function, e.g. ATP binding as a non-limiting example) to molecular level (e.g. phosphorylation activity ascribed to and domain of intact kinase function as a non-

limiting example) to the cellular level (e.g. modulation of cell death, as a non-limiting example).

(2) In examples 3, 4, 11 and 12 applicant exemplified multiple kinase activities for the polypeptides, including phosphorylation, reporter gene activation and the ability to affect nuclear factor –kB. According to applicant it is clear that 14171 activities are more than the ability to transfer a phosphate group to a substrate and therefore the rejection should be withdrawn.

These arguments were fully considered but were found **unpersuasive** because in response to applicant's **first** argument it should be noted that section [0088], indicated by applicant, refers to a laundry list of a series of protein kinase activities which are non-specific and can be applied to many kinases in the prior art. For example activities such as modulating cellular proliferation or the regulation of transmission signals from cellular processes do not specify which specific cells or which specific transmission signals are modulated or regulated. Therefore, such general and non-specific activities that can be applied to numerous kinases in the prior art, render "an activity" of "a kinase" activity confusing.

With respect to applicant's **second** argument applicant is reminded that firstly, the term "affecting nuclear factor –kB" is unclear. Secondly, many pathways such as "reporter gene activation" and "NfkB activation/deactivation" are not well defined in the prior art. Above mentioned examples are all "in vitro" or "in situ" examples focusing on one or a few isolated polypeptide(s) substrates, such as IL-8 in example 11 etc., the role of which being unknown in said pathways . Thus, such isolated "in vitro", "in situ"

experiments in the absence of identification of all members of said pathways cannot be relied upon for defining "an activity" of "a kinase" activity of 14171 polypeptides of this invention.

Allowable Subject Matter

Claims 21 and 35 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This is because SEQ ID NO:2 is free of prior art. Further the prior art does not teach or suggest such specifically claimed amino acid sequence. Hence said sequence is also non-obvious. Since said amino acid sequence is both novel and non-obvious, polypeptides comprising or consisting g of said amino acid sequence are also novel and non-obvious.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshi

Maryam Monshipouri Ph.D.

Primary Examiner